REMARKS

Introduction

Claims 1, 2, 9, 25-26, 28, 30-31, and 43 are pending and under examination. Claims 10-24, 27, 29, 32-42, 44, and 56-61 are pending but have been withdrawn. Claims 1, 28, and 29 have been amended. Support for these amendments can be found throughout the specification, for example, in the claims as filed and at paragraphs [0039], [0053], and [0056]. No new matter is believed to have been added.

Claims 3-8 and 45-55 are cancelled without prejudice to the subject matter therein. Applicant expressly reserves the right to pursue the subject matter of these claims in this application via rejoinder or in another application.

Rejections under 35 U.S.C. § 112

A. First Paragraph – Written Description

The Examiner has rejected claims 1-2, 9, 25-26, 28, 30-31, and 43 under the first paragraph of 35 U.S.C. § 112 as allegedly lacking sufficient written description. Applicants disagree. However, solely to expedite prosecution, claim 1 has been amended to recite the elected species "inhibitor of PKCα" as the Examiner suggested. The Examiner has not shown that one of skill in the art would recognize that Applicant was not in possession of the claimed invention.

The phrase "inhibitor of PKCα" has written description throughout the specification, for example, in the claims as filed and at paragraphs [0039], [0053], and [0056]. Applicant further exemplifies compounds belonging to this genus, such as, antisense oligonucleotides of the gene coding for PKCα, tocopherol, and phorbol compounds. See pg. 9, [0088].

Moreover, Applicant has also provided guidance on how to determine other members of the genus when Applicant states "'inhibitor' means a substance which competitively inhibits the

biological activity of protein kinase C-α, allosterically changes the spatial structure of PKC-α, or inhibits PKC-α by substrate inhibition." See pg. 6, paragraph [0056].

There is explicit written description support for the amended claims and sufficient guidance in the specification to allow persons of ordinary skill in the art to recognize that Applicant was in possession of what is claimed at the time of filing. Therefore, the amended claims have sufficient written description and this rejection is now believed to be moot. Its withdrawal is respectfully requested.

B. First Paragraph – Enablement

The Examiner has rejected claims 1-2, 9, 25-26, 28, 30-31, and 43 under the first paragraph of 35 U.S.C. § 112 as allegedly failing to comply with the enablement requirement. Applicants disagree. The basis for the Examiner finding a lack of enablement of the claims is not clear.

Moreover, Appendix A, which accompanies this response, contains data demonstrating that angiotensin-II does not significantly impair cardiac output in knock-out mice. Cardiac contractility in angiotensin-II treated wild type animals was significantly decreased, whereas in angiotensin-II treated knock-out mice contractility was nearly the same as in untreated wild-type or knock-out mice. This experimental data shows that PKCα is an important mediator of cardiac contractility and left ventricular hypertrophy. See page 4 of Appendix A, last sentence. Accordingly, the claimed methods of using inhibitors of PKCα are fully enabled for treating or preventing cardiovascular diseases. Applicant respectfully requests that this rejection be withdrawn.

Rejection under 35 U.S.C. § 102

The Examiner has rejected claims 1-2, 9, 25-26, 28, 30-31, and 43 under 35 U.S.C. § 102 as allegedly being inherently anticipated by U.S. Patent Number 5,871,766 issued to Hennekens (the '766 patent). The Examiner notes that the '766 patent is silent on the use of PKCα inhibiting

compounds but contends that such uses are inherently disclosed. It is respectfully submitted that the Examiner has not established inherent anticipation.

MPEP section 2112 states that the burden is on the Examiner to provide evidence of inherent anticipation. This MPEP section states that "[t]o establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities." Importantly, "[t]he mere fact that a certain thing may result from a given set of circumstances is not sufficient." MPEP section 2112, citing *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999).

The Examiner has not shown evidence in the '766 patent that suggests the administration of an effective amount of a PKCα inhibitor to treat cardiovascular disease. The '766 patent purports to teach the use of Vitamin E and the biologically active analogs thereof to inhibit major vascular events. See col. 4, ll. 42-43. These analogs include "molecules which demonstrate equivalent biological function but which differ structurally . . . [and] include all other tocopherols." See col. 4, ll. 42-46. The '766 patent does not provide working examples of using Vitamin E in treating heart disease and instead provides an example of the use of beta-carotene and/or aspirin.

Moreover, as the Examiner notes, the '766 patent is silent on the use of an effective amount of **inhibitors of PKCα** to treat or prevent heart disease. It merely purports to disclose the use of vitamin E, a term that encompasses at least eight different enantimeric compositions for tocopherols and tocotrienoles, to inhibit vascular events. The '766 patent does not disclose which Vitamin E analogs are effective in treating heart disease nor provide any guidance on which may inhibit PKCα. There is insufficient evidence in the '766 patent to demonstrate the effectiveness of **inhibitors of PKCα**, including tocopherol, in methods of treating cardiovascular disease or for one of skill in the art to appreciate such a use for inhibitors of PKCα. Without more evidence, the current inherent anticipation rejection is improperly based on probabilities and possibilities and not the requisite extrinsic evidence. Therefore, Applicant respectfully requests that the rejection of the claimed genus of **inhibitors of PKCα** based upon the '766 patent be withdrawn.

In view of the above amendment and arguments, Applicant believes the pending application is in condition for allowance.

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Respectfully submitted,

By _____

Matthew E. Kelley
Registration No.: 55,887
VENABLE LLP
P.O. Box 34385
Washington, DC 20043-9998
(202) 344-4000
(202) 344-8300 (Fax)
Attorney/Agent For Applicant

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